

Mandatory reporting by physicians of patients potentially unfit to drive

DONALD A. REDELMEIER, VIKRAM VENKATESH, MATTHEW B. STANBROOK

ABSTRACT

Background: One strategy for the prevention of motor vehicle crashes is physician reporting of medically unfit drivers to vehicle licensing authorities, as mandated by law in Ontario, Canada. We studied drivers involved in life-threatening crashes who required hospital admission to determine how many had previously been seen and reported by a physician in the community.

Methods: We identified consecutive drivers involved in a crash who were admitted to Canada's largest trauma centre between 30 June 1996 and 30 June 2001 to assess the prevalence of 3 chronic medical conditions reportable to vehicle licensing authorities (alcohol abuse, cardiac disease, and neurological disorders). We then conducted a case series analysis of linked health and transportation databases to determine how many drivers had previously been seen and reported by a physician in the community.

Results: A total of 1,605 injured drivers were identified, of whom 37% had a reportable condition (95% confidence interval [CI] 35–39). Those with a reportable condition had made a total of 20,505 previous visits to 2,332 physicians during the five years before the crash. The majority of patients with a reportable condition (85%, 95% CI 82–88) had seen a physician in the year before the crash but few (3%, 95% CI 2–4) had been reported to licensing authorities. Alcohol abuse was the most common underlying reportable condition (prevalent in 72% of trauma patients with a reportable condition) and the least common reason for a previous report (reported in 2% of those with a reportable condition).

Interpretation: Unsafe drivers often visit physicians and yet are rarely reported to licensing authorities even under mandatory reporting laws for preventive medical reporting.

Donald A. Redelmeier is a professor of medicine at Sunnybrook Health Sciences Centre of the University of Toronto, as well as a Senior Scientist at the Institute for Clinical Evaluative Sciences in Toronto, Ont. **Vikram Venkatesh** is a resident in radiology at McMaster University, Hamilton, Ont. **Matthew B. Stanbrook** is an assistant professor in respirology at the University Health Network of the University of Toronto, Toronto, Ont.

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Correspondence: Donald A. Redelmeier, Sunnybrook Health Sciences Centre, G-151, 2075 Bayview Ave, Toronto ON Canada M4N 3M5; dar@ices.on.ca

UNSAFE DRIVERS ARE A HAZARD TO SOCIETY and contribute to more than 100 motor vehicle fatalities every day in North America.¹ Medically unfit drivers are a notable subgroup because chronic conditions can impair a person's driving and increase the risk of a crash.²⁻⁵ Crashes in such cases often receive substantial public attention, especially if it comes to light that a driver who caused another person's death showed earlier warnings of impaired ability.⁶ Medically unfit drivers world wide kill more than 5,000 pedestrians each year.⁷ Restricting drivers who have medical conditions, however, is no simple task, given the size of this population sector, cultural attitudes toward mobility, the political power of older people, and the ambiguous definition of "medically unfit." A further complexity relates to self-restriction, whereby some drivers are more dangerous per mile but not per year.⁸⁻¹¹

One proposed solution is to restrict driving on the basis of medical diagnoses rather than age, activity, or vehicle ownership. Doing so has broad appeal because illness can lead to impairment and because unsafe driving imposes risks on others. Reporting by physicians avoids fallibility related to relying on the initiative of drivers, the impetus of family, or enforcement by police.¹² Yet physicians may be disinclined to report patients how are unfit to drive spontaneously, perhaps because of the tension between being an advocate for the patient and being a protector of society.¹³⁻¹⁵ Additional factors that contribute to a lack of reporting by physicians include uncertainty over what constitutes a significant impairment, worries about patient dissatisfaction, limited time, a lack of training, a presumption that unsafe drivers rarely visit physicians, and the traditional view that road safety is not a medical problem that merits preventive efforts by physicians.¹⁶⁻¹⁸

Ontario, Canada, has a broad law mandating physicians in the community to report any patient who "is suffering from a condition that may make it dangerous for the person to operate a motor vehicle."¹⁹ This amounts to an imposed affirmative duty,⁶ which is rare under Anglo-American law but analogous to mandatory reporting of suspected child abuse. As in some US jurisdictions, the onus is on physicians and courts have deemed physicians liable for failure to report unfit drivers.²⁰⁻²² In this study, we investigated physicians' compliance with the law by identifying drivers who presented to a large trauma centre and examined the previ-

ous care of patients who had reportable chronic conditions. Our hypothesis was that drivers involved in serious crashes often have impairments, frequently visit physicians, yet are rarely reported.

Methods

General setting. In 2002 Ontario had a population of about 12 million people, 8.4 million licensed drivers, and 9,000 primary care physicians. During that year 200,000 crashes occurred, resulting in 873 fatalities.²³ Fewer than 0.1% of Ontario drivers per year had their license reviewed for medical conditions.²⁴ Conditions requiring notification were uniform in all regions as set out in section 203[1] of the *Highway Traffic Act* (first enacted in 1968), and pertain to generalist and specialist physicians. The regulations underwent no amendments during the study and were endorsed by local and national medical regulating bodies. Similar to other mandatory reporting laws, physicians were not expected to be accurate or precise in diagnoses but were obliged to notify licensing agencies so that a review by a separate board could be conducted.²⁵ Physicians reporting in Ontario were protected against legal liability for the associated breach of patient confidentiality.²⁶

Included patients. We identified consecutive trauma patients admitted to Canada's largest trauma centre, Sunnybrook Health Sciences Centre, because this hospital receives trauma patients from crashes throughout Ontario (based on Injury Severity Scores of 13 or higher) and regardless of chronic conditions.²⁷ The accrual interval spanned 30 June 1996 to 30 June 2001 to provide sufficient sample size and observation time before the day of the crash. We included only individuals in the driver's position at impact because passengers and pedestrians would not be directly targeted by policies regarding restricted licenses. Drivers of motorcycles were included; drivers of bicycles, snowmobiles, and recreational vehicles were excluded since they are not the usual consideration of regulations for unfit drivers. All screening was conducted blind to at-fault considerations such as excessive speed, driver inattention, improper lane change, or other non-medical fallibilities.

Individual characteristics. We obtained baseline data for each patient by chart review at the trauma center using a structured explicit standardized approach with inbuilt software checks, real-time iteration

and regular random audits.²⁸⁻³¹ The time and location of the crash were based on paramedic reports. We used admission, progress, and discharge records (including nursing, social work, and other professionals) for ascertainment of alcohol abuse as evidenced by patient report, collateral family history, findings on examination, or positive testing.³²⁻³³ Similarly, clinical evaluation at the trauma centre provided evidence of antecedent cardiovascular diseases (unstable angina, chronic arrhythmia, stroke, or extensive vascular disease) and neurological disorders (dementia, seizure, mental retardation, or active psychiatric disorders).³⁴⁻³⁵ We did not include sleep disorders, metabolic diseases, vision or hearing limitations, musculoskeletal disabilities, and general debility because these are difficult to determine in the aftermath of a crash.³⁶ Throughout, we counted only conditions judged by the responsible trauma physician as chronic and contributing to the patient's injury.

Database linkages. We linked patients to their Ontario Health Insurance Plan records by using an encrypted version of their individual health card number.³⁷ Matches were checked by verifying birth date and included spot checks to reconcile inconsistencies in name (e.g., "William" and "Bill"). Faulty or missing matches were addressed by manual searches according to first name, last name, birth date, and sex. Similar methods were used to link each patient to Ministry of Transportation records connecting to driver licences (with reconciliations denoted as "probable" and "possible" matches according to government protocols housed at the Ministry of Transportation). This project was approved by the research ethics committee of Sunnybrook Health Science Centre and conducted according to confidentiality protocols of the Institute for Clinical Evaluative Studies in Ontario.

Previous health care. We searched each person's records backward in time from their crash until 1 July 1991 (start date of the health care database) to identify previous outpatient visits to a physician anywhere in Ontario. If the patient had multiple prior visits we also analyzed the visit that most closely preceded the crash. For the prior visit we recorded the date, diagnostic category, fee code, and a unique identifier for the physician providing the visit. Finally, because trauma charts can be fallible, we also conducted a comprehensive analysis of all past outpatient and inpatient records for any men-

tion of alcohol abuse, cardiac disease, or neurological disorders.

Previous driving reports. Past reports on driving notifications, restrictions, and suspensions were obtained by contacting the Driver Improvement Office of the Medical Review Section of the Ontario Ministry of Transportation. Special attention was again directed to avoid faulty or missing matches using the standardized in-house protocols of the Ministry of Transportation. Governmental transportation records were then searched backward from the crash date for any reported notification of the individual patient by a physician. These analyses were conducted blind to whether the patient had a reportable condition when examined in the trauma centre. For each notification we extracted information about the interval between the previous notification and the subsequent crash. We did not have data on either the process or the outcome of cases reviewed by the Ministry of Transportation.

Statistical analysis. The primary outcome was the prevalence of previous reporting to the Ministry of Transportation among patients with reportable conditions. No adjustment was made for misclassification of patients who might have been incompletely documented at the trauma centre and incorrectly classified as having no reportable condition. Categorical data were compared using the chi-square test, continuous data using the *t*-test, and time intervals using the Kaplan-Meier technique. All statistics were two-tailed estimates and based on all available data.

Results

General overview. A total of 4,208 patients were admitted to the trauma centre during the 5-year interval, of whom 1,605 were drivers involved in motor vehicle crashes and included for analysis. No repeat hospital admissions were observed in the study cohort during the study interval. Validated outpatient health care record linkages could be verified for 97% as a definite match (unmatched = 3%). Validated driver record linkages could be verified for 80% as a definite match, 10% as a probable match, and 2% as a possible match (unmatched = 8%). In total, 596 individuals had reportable conditions documented at the trauma centre and 1,009 did not have a reportable condition. The most common reportable condition was alcohol abuse (72%), followed by cardiac disease (23%) and neurological disorders (5%).

Table 1: Patient characteristics

		Reportable condition absent* (n = 1009)	Reportable condition present* (n = 596)
Age (years)	< 25	283 (28)	115 (19)
	25–44	443 (44)	247 (41)
	45–64	219 (22)	147 (25)
	≥ 65	64 (6)	87 (15)
Sex	Female	272 (27)	115 (19)
	Male	737 (73)	481 (81)
Injury severity score§	< 15	305 (30)	170 (29)
	15–24	266 (26)	170 (29)
	25–34	228 (23)	145 (24)
	≥ 35	210 (21)	111 (19)
Charlson comorbidity score¶	0	848 (84)	485 (81)
	≥ 1	55 (5)	55 (9)
	Missing	106 (11)	56 (9)
Blood transfusions (units)†	≥ 1	335 (33)	195 (33)
	≥ 5	204 (20)	113 (19)
Surgical procedures‡	≥ 1	604 (60)	329 (55)
	≥ 2	273 (27)	133 (22)
Length of stay (days)†	< 3	206 (20)	131 (22)
	3–6	182 (18)	115 (19)
	7–14	301 (30)	168 (28)
	≥ 15	320 (32)	182 (31)
Trauma outcome	Death	84 (8.3)	53 (8.9)

Data are presented as count (percentage) of each group.
 * as identified by trauma centre charts
 † analyzed as potential proxy for injury severity
 § range from 0 to 75; greater values indicate worse injuries
 ¶ range from 0 to 33; greater values indicate more comorbidity

Injury comparisons. The average driver with a reportable condition was marginally older and more likely to be male than those who did not have a reportable condition (Table 1). The two groups required a similar number of units of blood transfused on average (2.1 vs 2.4, respectively), corresponding to a relative difference of about 12% (95% CI -4 to 29) and further suggesting that injury severity was substantial in both groups. Patients with reportable conditions averaged marginally fewer trips to the operating room (0.9 vs 1.1, respectively) but a similar median length of stay (14 days vs 14 days, respectively). The patients with reportable conditions accounted for a total of 53 deaths, 551 surgeries, 1252 units of blood, and 8440 hospital days (corresponding to about \$3 million in hospital costs).³⁸

Previous visits. About 98% of all patients (n = 1537) had previously visited a doctor, of whom 83% had visited in the previous year and 14% in the previous week. The total number of visits in the last 5 years for any reason among those with reportable conditions was 20,505, reflecting contact with 2,332 distinct physicians. More than 80% of all patients had at least one mention of a reportable condition when based on database linkage rather than trauma chart review (Table 2). Almost half of all patients had 5 or more visits in the year immediately before the crash. The most common reasons for the most recent previous visit for all patients were respiratory tract infections, minor injury or general care. The most common professional code for all visits, an “intermediate assessment,” did not differ between the two groups and corresponded to a physician fee of \$24.80.

Table 2: Reasons for previous physician visits §

	Reportable condition absent * (n = 979)	Reportable condition present * (n = 585)
Total count of visits in previous 5 years	25215	20505
Patients with ≥ 5 visits	830 (85)	510 (87)
Patients with ≥ 10 visits	662 (68)	438 (75)
Patients with ≥ 20 visits	435 (44)	320 (55)
Diagnoses from previous visits ¶		
Any reportable condition	769 (79)	518 (89)
Alcohol abuse	61 (6)	161 (28)
Cardiac disease	507 (52)	393 (67)
Neurological disorder	611 (62)	379 (65)
Physician attended in previous 5 years		
General practitioner	922 (94)	561 (96)
Internal medicine **	206 (21)	206 (35)
Psychiatry	82 (8)	76 (13)
Total count of visits in previous 1 year	5492	4517
Patients with ≥ 5 visits	367 (37)	281 (48)
Patients with ≥ 10 visits	169 (17)	145 (25)
Patients with ≥ 20 visits	47 (5)	57 (10)
Diagnoses from most recent visit †		
Respiratory	148 (15)	53 (9)
Cardiovascular	29 (3)	44 (8)
Gastrointestinal	32 (3)	27 (5)
Genito-urinary	44 (4)	18 (3)
Musculoskeletal	60 (6)	42 (7)
Endocrine	34 (3)	21 (4)
Dermatologic	77 (8)	26 (4)
Infectious	51 (5)	28 (5)
Neoplastic	18 (2)	6 (1)
Injury	117 (12)	77 (13)
Neurologic	57 (6)	34 (6)
Psychiatric	65 (7)	59 (10)
Supplementary categories	27 (3)	10 (2)
Ill-defined conditions	26 (3)	11 (2)
Diagnosis not required	170 (17)	118 (20)
Diagnosis missing	24 (2)	11 (2)
Total count of hospital admissions in previous 5 years	337	433
Patients with ≥ 1 admissions	187 (19)	170 (29)
Patients with ≥ 5 admissions	10 (1)	17 (3)
Data are presented as count (percentage) of each group except as noted.		
* as identified by trauma center charts		
§ excludes those with no previous visits (n = 30) and (n = 11)		
¶ any mention in outpatient billing record and not necessarily most responsible diagnosis		
† classified by most responsible diagnosis		
** includes cardiology and neurology		

Mandatory reporting. A total of 28 of the 1,605 patients were reported by physicians to the Ministry of Transportation prior to their crash. The overall frequency of reporting for those with reportable conditions was only marginally higher than the baseline frequency for those without reportable conditions (3% vs 1%, $p = 0.003$). This non-zero baseline frequency was explained by routine reporting of those with commercial driver licenses (for

whom mandatory reports must be filed). The highest frequency of reporting was for patients diagnosed with neurological conditions (6/29, 21%) and the lowest frequency of reporting was for patients diagnosed with alcohol abuse (7/429, 2%). No other patient characteristic (Table 1) was independently associated with rates of reporting. The median lag between the prior report and the patient's subsequent crash was 3.5 years (95% CI 2.4–4.5).

Interpretation

We studied drivers involved in life-threatening motor vehicle crashes to assess physicians' compliance with mandatory reporting in real-world circumstances. We found that about one-third of trauma patients had a prior medical condition that might have impaired their ability to operate a motor vehicle, may have contributed to injury, and was potentially reportable to licensing authorities. Almost all these drivers had seen a physician before the crash. In contrast to the prevailing law, almost none of these drivers were reported by physicians to licensing authorities (and the few reports were made more than 3 years prior to the crash). Alcohol abuse was the most frequent reportable condition contributing to a serious crash (with a rate similar to that reported in past literature³⁹) and the least frequent reason for notification.

The largest limitation of our research is the fallible manner of ascertaining chronic medical conditions in trauma patients. The Ontario law is written using vague language ("a condition that may make it dangerous"), which could be interpreted to include minor issues of any severity. Our specific list of reportable conditions was based on the Canadian Medical Association handbook³⁴ but did not include all diseases (e.g., sleep apnea). Our methodology relied on chart review, which is prone to false negatives. The specific charts reviewed were from a trauma service, a setting in which attention may not focus on chronic conditions and where detailed medical ascertainment is sometimes not feasible. Together, these limitations imply that our study is conservative in design and underestimates the extent of under-reporting of drivers to licensing authorities.

The data could have underestimated physicians' compliance with the law if multiple other unobserved patients visited a physician during the same interval, were reported to licensing authorities, and subsequently renounced driving. However, this possibility is unlikely for three reasons. First, the total frequency of reporting is low, far below the prevalence of conditions in the population. Second, alcohol abuse is the most common reportable condition we observed in drivers, yet it is notoriously difficult to detect in primary care and notoriously linked to poor compliance with restrictions. Third, the relative risk of a crash from unreported cardiac and neurological conditions would need to be unrealistically high (odds-ratios beyond 100) to have these conditions both commonly present yet rarely reported in unobserved non-trauma patients (Appendix).

Our research suggests that opportunities to prevent serious crashes are missed by physicians even in communities with mandatory reporting (seven provinces and all territories in Canada have such laws). Physician under-reporting in this study could have several explanations. An intent to preserve the patient's quality of life can explain some cases, but would not explain the extent of under-reporting given that the driver is the most common person disabled in a crash in North America.^{1,40} A lack of attention is another explanation, since patients rarely seek care for a driving assessment.⁴¹ The failure to report unfit drivers also indicates that reporting requirements are not straightforward (similar to the interpretation needed when reporting aviators, air traffic controllers, and selected railway workers).^{42,43}

Our findings agree with anecdotal reports, editorials, and depositions that physicians are unsure in many cases about when to report medically unfit drivers and that mandatory laws do not eliminate this uncertainty.⁴⁴⁻⁴⁷ Moreover, physicians don't have all the scientific evidence: the contribution of many diseases to driver risk is speculative, risk will vary if the condition is inactive or under control, and the Ministry's own reporting form provides little data for guidance.⁴⁸ Physicians are often unaware of each patient's driving abilities (e.g., attention), impairments (e.g., alcoholism), or attitudes (e.g., speeding) and thereby cannot form a judgment of dangerousness.^{49,50} A crackdown to increase reporting by physicians, moreover, might deter patients from seeking medical care.⁵¹ When it comes to a patient's driving habits, for example, doctors are less knowledgeable than family members in many ways.

Reporting benefits have limitations even if clinicians are perfectly knowledgeable about their patients, equipped with solid scientific evidence, and fully compliant with the law: healthy young adults still represent the majority of crashes and have no reportable conditions.⁵²⁻⁵⁴ Drivers who have reportable conditions may over-contribute to crashes relative to the general population, yet the associations are not overwhelming. Further, drivers who are reported to authorities are not always compliant with restrictions.⁵⁵⁻⁵⁷ Also, licensing authorities can become overworked and may make fallible judgments about exemptions and reinstatements. Finally, mandatory reporting laws impose affirmative duty on physicians using broad language and thereby conceivably extend to almost every patient seen in practice.

Our study also underscores how difficult it is to conduct research to test whether legislation has achieved its

intended effect. Evaluations cannot be designed as randomized blinded trials, since this would violate the principle of uniform justice. Many years need to elapse between the enactment of a law and subsequent evaluation to provide sufficient sample size and eliminate chance findings. Lawmakers who enact legislation also have little incentive to follow up and check on anticipated consequences or adverse effects. No study applies universally due to the subtleties of culture that vary across regions. Finally, the indirect deterrent effect upon other individuals, the alternative uses for finite legal resources, and the theoretical effectiveness under ideal circumstances are inevitable questions that are difficult to study in a quantitative manner.

In summary, our data suggest that mandatory reporting in Ontario does not achieve its stated purpose; however, the data do not indicate whether regulations should be reduced or expanded. Reducing regulations would decrease the liability for physicians and might encourage attention toward alternative safety policies such as roadside police or periodic driver testing. Expanding regulations would extend societal participation—analogue to suspected child abuse laws—by obliging others in the community to notify authorities regarding mishaps (e.g., hospitals, vehicle insurers or mechanics). Less radical changes are possible that might focus on screening, detection, and counselling with respect to alcoholism.^{58,59} In the absence of policy changes, physicians seem mostly inclined toward resuscitation and treatment in the aftermath of a crash.

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Appendix

Overview

The purpose of this appendix is to explain how extreme postulates about patients who stop driving do not vitiate our observation that physicians rarely comply with the mandatory reporting law. The intended audience is reviewers seeking technical details. We structure the analysis by making specific assumptions in favour of physicians and show how doing so does not yield a pattern of results sufficient to explain the findings. We next introduce a general model for testing ranges and combinations of assumptions in favour of physicians and again show a pattern of results insufficient to explain the findings. Throughout we distinguish three types of drivers: namely, drivers with reportable medical conditions that are not detected by physicians; drivers with reportable medical conditions that are detected by physicians; and drivers with no reportable medical conditions. We also reiterate that the law mandates physicians to notify licensing authorities about all patients with a reportable condition regardless of clinical judgment, disease severity, or patient preference.

Specific example

Our analysis uses the strategy of proof-by-contradiction. Consider a community of a million drivers. Assume that 5% of drivers have a reportable condition (e.g., alcoholism, dementia). Assume that the overall baseline annual risk of a crash among drivers in the community is 1%, that those who have a reportable condition that goes undetected are at triple the baseline risk (relative risk = 3.0), and that those who have a reportable condition that is detected and reported are at one-half the baseline risk (relative risk = 0.5). These assumptions are in line with available epidemiologic evidence (same order of magnitude). Now, assume that physician compliance with the mandatory reporting law in the community is 80%. This last assumption provides a favourable characterization of physician diagnostic acumen, diligent counselling and notification, and commensurate follow-through by licensing authorities. This favourable assumption, however, leads to multiple contradictions against available information.

The specific data imply that 50,000 drivers ($1,000,000 \times 5\%$) have a condition that justifies reporting to licensing authorities, of whom 40,000 would be detected by physicians ($50,000 \times 80\%$) and 10,000 would not be detected by physicians ($50,000 \times 20\%$). Drivers with no reportable condition contribute to 9,500 collisions ($950,000 \times 1\%$). Drivers with a detected condition contribute to 200 collisions ($40,000 \times 1\% \times 0.5$). Drivers with undetected conditions contribute to 300 collisions ($10,000 \times 1\% \times 3.0$). Observe three anomalies. First, the rate of reporting would be about 4% ($40,000 / 1,000,000$). This rate is much higher than the observed rate below 0.1% in Ontario. Second, the prevalence of reportable conditions in the trauma centre would be about 5% ($[200 + 300] / [9500 + 200 + 300]$). This rate is much lower than the observed rate of 37% in our study. Third, the frequency of previous reports among those with reportable conditions in the trauma centre would be about 40% ($200 / 500$). This rate is much higher than the rate of 3% observed in our study.

General model

The numerical estimates in the preceding example were uncertain. Hence, replace with five variables (A, B, C, D, E). Let A be the prevalence of reportable conditions in the community (in example, $A = 5\%$). Let B be the baseline risk of a crash (in example, $B = 1\%$). Let C be the relative risk of a crash for drivers with reportable conditions that go undetected (in example, $C = 3$). Let D be the relative risk of a crash for drivers with reportable conditions that are detected (in example, $D = 0.5$). Let E be physician compliance with mandatory reporting (in example, $E = 80\%$). The model yields three outputs verifiable by licensing authorities or an epidemiologic study. Let “overall rate” be the overall rate of reporting by physicians to licensing authorities (in observation, overall rate $< 0.1\%$). Let “prevalence disease” be the prevalence of reportable conditions at the trauma centre (in observation, prevalence disease = 37%). Let “prior reporting” be the frequency of prior reports at the trauma centre among those with reportable conditions (in observation, prior reporting = 3%).

The general model has five variables (A, B, C, D, E) that must satisfy three constraints (corresponding to the three observations). Exact computational solutions are cumbersome because each of the three observations has an accompanying degree of measurement error. Hence, solutions are more easily tackled using constrained nonlinear programming such as through computer simulations. An example spreadsheet can be constructed by readers using the above parameters or can be obtained from the authors on request. For iterative analyses, we used a wide range for plausible values of each variable: A: (1% to 50%); B: (0.1% to 10%); C: (1.0 to 10.0); D: (0.1 to 10.0); and E: (1% to 100%). The purpose of these analyses was to identify the circumstances that maximize the value of variable E, physician compliance with mandatory reporting. The hypothesis was that even extreme assumptions about variables A, B, C, D yield maximal values of E that are still modest.

Several subsequent findings were intuitive. We found that variable E was maximized when A was minimized, C was maximized, and D was minimized. These three results imply that physicians seem most compliant if reportable conditions are rare in the community and are associated with a large increase in the driver's crash risk, and that detection results in a large net decrease in the driver's crash risk (100-fold reduction possible using the above ranges). We found that variable E was unaffected by extreme ranges in variable B. We also found that the maximum variable E obtained was less than 5%. That is, even extreme assumptions about prevalence, baseline risk, and relative risks for drivers with and without detected conditions could not yield an optimistic estimate of physician compliance with the mandatory reporting law. Incidentally, we checked values outside the plausible range and found a near-solution (A: 0.2%; C: 500; D: 15) that yielded an overall unmeasured physician compliance of 50%. This out-of-bounds compliance rate of 50% would still represent a large violation to the prevailing law.

Epidemiologic inference

The intent of epidemiologic research is to find associations in observable data. Associations that cannot be attributed to unobserved data are classified as having the property of sufficiency. A randomized trial design with a large sample size has sufficiency because the laws of probability tend to make the unobserved data balanced between the intervention and control groups. A cohort study design that observes a large gain in outcomes that favours the intervention group has sufficiency if baseline imbalances are all biased against the intervention group so that unobserved data cannot lead to countervailing confounding. A case series design rarely has sufficiency; instead, the lack of a control group may lead to over-interpretation if plausible unobserved confounders are ignored. A case series design generally has sufficiency to establish what can possibly happen, but a case series design does not have sufficiency to establish what must happen (or what must not happen).

Our case series about physician compliance with mandatory reporting has sufficiency because of three special conditions. First, the law in Ontario is extreme, so that a physician who fails to notify licensing authorities about any patient can be classified as violating the law. Second, the observed reporting rate in our trauma study is extreme, so that 97% of trauma patients failed to be reported to licensing authorities despite previous visits to physicians in the community. Third, the two extremes are in opposite directions so that the plausible confounder of unmeasured driver compliance is unable to reconcile the discrepancy. Note that our study can have the property of sufficiency without commenting on causality because the research is descriptive rather than interventional. Incidentally, this sufficiency also leads indirectly to difficulties with some potential alternative designs, such as case-crossover analyses, case-control analyses, and ecologic analyses.

Summary

In our study we evaluated physicians' compliance with mandatory reporting laws. In this appendix we calculated how extreme assumptions about unobserved drivers could not explain the pattern of results. Hence, unmeasured driver and physician behaviour cannot be postulated as an important offsetting confounder. In other words, the population-based case-series design is sufficient to indicate that physicians rarely comply with mandatory reporting laws. In turn, regulatory methods for improving public safety generally require a chain of compliance whereby each fallibility decreases the ultimate effectiveness of the regulation. Perfect compliance downstream (by patients with suspensions and by licensing authorities with administration) does not compensate for the shortfall in compliance by physicians. As a consequence, the effectiveness of mandatory reporting under current circumstances is limited.